

SPL Process ER/DL Meeting

Meeting Minutes

May 21, 2014

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Animal OTC drug listing: Animal OTC drug listings - still voluntary? Are there any guidances or minutes specific to this? (Ken Stevenson)

Meeting Discussion:

- Charisse Kasser:
 - i. Animal OTC are mandatory.
 - ii. Only difference is that there are no monographs.
 - iii. They must reference the API manufacturer.
 - iv. SPL difference: don't do establishment by product. You don't have to link the NDC numbers to each registration.

2. Human OTC drug listing: Approach by client who is purchasing a lot of OTC from a foreign manufacturing. They want to relabel the product after purchasing. (Ken Stevenson)

Meeting Discussion:

- Are there any pitfalls to repacking and relabeling? The client has to be registered as a repacker and relabeler for the establishment – and the product must have a new NDC.
- SPL should also reference the NDC /source code of the original manufacturer.
- Need to reference their NDA/ANDA.

3. Importing: Share recent learnings about importing goods thru Atlanta, and what is needed from the drug listing side. Many may already know this, or be going thru the same difficulties, but thought it might be a nice to give a heads up to any who haven't run across this yet. (Ben Harpster)

Meeting Discussion:

- CDER based products going through FDA port of entry of Atlanta.
- They are now going back to the paper system.
- If your API and final product is manufacture outside the US, you will have to provide 3 NDCs on the import documents:
 - i. API bulk listing (New, with API site labeler code)
 - ii. Foreign product NDC drug listing. (New, with mfg labeler code – analogous to a PLD)
 - iii. Final distributed product.
- Ava from Pfizer is experiencing the same thing – importing through Atlanta. They had been listed formerly as paper listing, but they weren't recognizing the paper listing.
- Perigo is seeing the same thing through Chicago. Foreign manufacturer has to have its drug listing.
- Merck is also having same issues.
- Bottom line: Anything that was listed in paper, needs to be listed electronically. Regs didn't change, but the electronic is that the NDC directory is no longer being updated. So if you wanted your drug to appear in the NDC directory, you need to drug list it electronically.
- Also, CMS put out a letter several years ago, saying it wouldn't pay for anything that isn't drug listed electronically.
- Issue is that the various import sites are implementing this consistently. Companies are having different experiences.
- Pat to call Paul Loebach to discuss the requirement to drug list API, even when the API is not being imported directly.

4. Implementation of new processes and data – how are these being communicated? (Ava Johnson)

Paper listings:

- Paper listings. some officers at the port are not looking at what has previously been paper listed and even after proving that a product or manufacturer has been paper listed they are still pushing back and are requiring an elisting.

CPP:

- The Export Certificate Team is also not accepting CPP (Certificate of Pharmaceutical Product) request because they are unable to locate elistings. A colleague at Pfizer had thirty requests for API CPP's rejected. These API's were old and were paper drug listed. We confirmed with FDA that they were listed and submitted the request again to the Export Certificate team and discussed with them our strategy which was to include NDC codes and to resubmit. They agreed with this approach and we resubmitted. They rejected again.

Meeting Discussion:

Paper listings:

- FDA has never told us directly to list the old paper stuff electronically. They have done this indirectly through (1) paper NDC system is no longer available/updated; (2) CMS is not reimbursing product that is not drug listed electronically.

CCPs:

- Based on the discussion above, it looks like you will have to submit the API drug listings electronically.

5. Walk ins: None